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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,542	10/11/2005	Yoshihito Hagawa	64291 (71719)	2577
21874 7590 05/12/2010 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
WARE, DEBORAH K				
ART UNIT		PAPER NUMBER		
1651				
MAIL DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/552,542

**Applicant(s)**

HAGAWA ET AL.

**Examiner**

DEBBIE K. WARE

**Art Unit**

1651

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 27, 30, 33, 36, 37, 43 and 47-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27, 30, 33, 36, 37, 43 and 47-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 27, 30, 33, 36-37, 43 and 47-50 are presented for reconsideration on the merits.

#### ***Response to Amendment***

The amendment filed February 1, 2010, has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Election/Restrictions***

Applicant's election **without** traverse of Group I, claims remaining 27, 30, 33, 36-37, 43, and 47-48 in the reply filed on March 11, 2008, is acknowledged. All non-elected claims have been canceled.

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. This case is a 371 of PCT/JP04/05089 filed April 8, 2004, and the Japanese document from which foreign priority is claimed from is dated April 8, 2003.

#### ***Information Disclosure Statement***

The information disclosure statements (IDSs) submitted on October 11, 2005 and April 3, 2007 have been received and entered. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27, 30, 33, 36-37, and 49-50 are rejected under 35 U.S.C. 103(a) as obvious over Sobol et al (6953574) in view of EP 1 112 692 A1.

Claims are drawn to a feed supplement comprising a lactic acid bacterium belonging to *Lactobacillus gasseri* OLL 2716 prepared on a medium containing whey. The feed supplement wherein the culture is a liquid product or dried product prepared by lyophilisation (freeze drying or spray drying methods). The supplement can further contain milk component.

Sobol et al teach a feed supplement, note col. 5, lines 60-63, wherein the supplement contains *Lactobacillus gasseri* bacterium, note col. 7, line 62. The culture is obtained by adding the bacterium to a medium containing whey protein, col. 5, lines 20-25 and col. 6, lines 45-46, 54-58 and col. 6, lines 65-67; and col. 7, lines 3-6, wherein a neutralization culturing is disclosed because the pH of the culture medium is held near 7.0 (i.e. 6.5), of which will neutralize the culture. Also note col. 7, lines 45-55 and 65-62. Also note col. 9, lines 9-19 wherein the sediment or treated product if you will is formed into a dried product wherein the treated product is lyophilized (i.e. freeze dried). The supplement is useful for treating intestinal diseases, note col. 10, lines 65-67. The supplement further comprises a milk component too, see col. 5, line 29. Further, the supplement is used on farms in animal husbandry, col. 5, lines 50-54, such as livestock (e.g. calf).

EP '692 teaches *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) useful in a food product, and furthermore that the *L. gasseri* can be pulverized or crushed, note page 9, [0033], lines 34-39.

Claims differ from Sobol in that the specific strain of *L. gasseri* is not disclosed, nor is the crushed form of the *L. gasseri*.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to select for the feed supplement of Sobol et al the specific strain *L. gasseri* OLL 2716 as disclosed by EP '692 because the specific strain is disclosed to possess pharmaceutical efficacy for food products. Therefore, to select for the specific strain, one of skill in the art would have expected successful results for its

use in a feed supplement as claimed herein. Each of the claims are taught, or at least suggested, by the cited prior art. In the absence of persuasive evidence to the contrary the claims are deemed *prima facie* obvious over the cited prior art.

Claims 43 and 47-48 and 50 are rejected under 35 U.S.C. 103(a) as obvious over Racek (US 2002/0146399) in view of Sobol et al and EP' 692, cited above.

Claims are discussed above and are further drawn to a feed supplement wherein the culture contained by it (the supplement) is obtainable by inoculating the bacterium to a medium containing whey protein and the treated product can be a freeze dried product and further the feed supplement contains an excipient which is a starch.

Raczek teaches a feed supplement comprising a lactic acid bacterium belonging to *Lactobacillus gasseri*, note abstract, page 2, columns 1-2, [0012], lines 2-3, [0013], lines 3-5, [0014], lines 1-2 and 10-11 and [0036], line 1, and page 3, column 1, [0054], lines 12-14 and [0055], lines 1-2 and method taught at page 4, column 2, claims 11 and 12-15, (especially note claim 13) for administering to a calf (e.g. a young livestock), note page 3, [0055], lines 1-2.

Sobol et al teach a feed supplement, note col. 5, lines 60-63, wherein the supplement contains *Lactobacillus gasseri* bacterium, note col. 7, line 62. The culture is obtained by adding the bacterium to a medium containing whey protein, col. 5, lines 20-25 and col. 6, lines 45-46, 54-58 and col. 6, lines 65-67; and col. 7, lines 3-6, wherein a neutralization culturing is disclosed because the pH of the culture medium is held near 7.0 (i.e. 6.5), of which will neutralize the culture. Also note col. 7, lines 45-55 and 65-62. Also note col. 9, lines 9-19 wherein the sediment or treated product if you will is formed

into a dried product wherein the treated product is lyophilized (i.e. freeze dried). The supplement is useful for treating intestinal diseases, note col. 10, lines 65-67. The supplement further comprises a milk component too, see col. 5, line 29. Further, the supplement is used on farms in animal husbandry, col. 5, lines 50-54, such as livestock (e.g. calf).

EP '692 teaches *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) useful in a food product, and furthermore that the *L. gasseri* can be pulverized or crushed, note page 9, [0033], lines 34-39.

The claims differ from Raczek in that the specific strain in whey is not clearly disclosed.

It would have been obvious to one of ordinary skill in the art to select for the method of Raczek the feed supplement of Sobol et al using the specific strain of EP '692 to improve intestinal flora of a young livestock such as a calf because the prior art clearly teach that *L. gasseri* is useful in animal feed and the strain OLL 2716 has also shown success in food as well. Therefore, one of skill would have expected successful results since each of the claim features are taught, or at least suggested, by the cited prior art combination as discussed herein and above.

The treatment of young livestock is common place in animal husbandry because of its relationship to animal rearing, and treating method using the disclosed supplement for a calf is intrinsic to the teaching of animal husbandry by Sobol et al. The treatment of a calf would have been an obvious modification of the cited prior art. A treated product is further disclosed and can be dried by lyophilization which is a form of freeze

drying or can be performed by drum drying, as disclosed by EP '692, see page 5, [0014], lines 1-5. The treated product can be in liquid or dry form as well. The milk component clearly reads on the claimed presence of an excipient ingredient. In the absence of persuasive evidence to the contrary the claims are deemed prima facie obvious over the cited prior art.

### ***Response to Arguments***

Applicant's arguments filed February 1, 2010, have been fully considered but they are not persuasive. The KSR argument with respect to strain OLL 2716 is noted, however, the strain is well known in the art for use with food/feed and having disinfecting properties for harmful bacteria in the gut. Therefore, it would have been expected to have probiotic activity and like properties, and hence useful as a feed supplement. Also it is the same species as disclosed by Sobol for use in a supplement feed; thus, while it may be a different strain of the species, the species as a whole is predictably recognized to be used in feed as supplement, therefore. The functions of the strain from the same species would have been expected to provide successful results and hence the results are predictable.

To select OLL 2716 is merely a matter of judicious selection and well within the purview of an ordinary artisan to select from well known equivalents for the same functional use well recognized by the cited prior art. Further, it would have been expected to have pharmaceutical efficacy as many probiotics do have and which is well known in the art. Probiotic activity clearly suggests enhancement of intestinal flora-improving activity. Animal studies are conducted with probiotics before they are used in



humans and hence the use of strain OLL 2716 in animals would have been expected to provide successful results. The cited prior art at least suggest, if not teaches, the claimed invention at the time it was made and renders the claims *prima facie* obvious.

The art specifically teaches the strain having probiotic activity or at least suggests it in the art. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The arguments are not persuasive and the rejection is sustained.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

The remaining references listed on the previously enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DKW/  
Deborah K. Ware  
Examiner  
1651  
/David M. Naff/

Primary Examiner, Art Unit 1657